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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/862,424

Applicant(s)

MARKOWITZ, VICTOR M.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15-28 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15-28 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed February 02, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. This is a NON-FINAL Office Action.

3. Claims 1, 15-28, and 35-41 are examined on the merits.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 15, 16, 21-24, 28, and 35-37 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Eckman et al. (1998).

6. Eckman et al. discloses a method of using a computer program product (page 3, column 2, Hardware and Software §) wherein the gene expression data (EST) is divided into plurality databases (pages 3-4, Data Sources §, and Figures 1 and 2) and grouped into at least two fragment classes according to accession number and quality analysis as exemplified by the Local relational database disclosure (page 4, column 1, lines 14-30). The attributes used for grouping

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said fragments are: assigned integer identifier and the GenBank accession number of its representative EST sequence, and results of pairwise BLAST comparisons between all EST sequences (unknown) and all known nucleic acid sequences (page 4, column 2, lines 1-24). The method of Eckman et al. is directed to determining the differential tissue expression for 12,000 distinct genes of the human genome (expression level, fold change, and up/down regulation)(page 3, column 1, The Merck Gene Index §).

7. The method of Eckman et al. is directed toward a data integration (links) effort comprising data from IMAGE clones in a relational database and dbEST sequences organized by sequence comparison results (page 3, column 2, Data Integration §). LENS provides a mapping between EST/cDNA clone identifiers from dbEST, GDB, GenBank, WashU and IMAGE databases.

8. The computer program product of Eckman et al. has library information (sample) which indicates the tissue type used as the source of the clone (page, 7, Clone data module §) and highly targeted query wherein a user can “retrieve all index classes which are differentially expressed in breast, are similar to known GPCRs or contain a TM7 motif, and are mapped to chr 8q12” (page 12, column 1, lines 3-8). The search results presents two reports: classes represented by ESTs of interest and ESTs that have no index class assignment (page 8, column 2, lines 8-10) (unknown), as in instant claims 1, 21, 35, and 37.

9. The inclusion of a document by Lodish et al. is not used as prior art, but only to expand on GPCR as directed gene pathway (Figure 20-6), as in instant claims 15, 22, 23, and 36.

10. “It assume that an EST or set of ESTs has already been identified by preliminary gene-finding efforts (first sample set) and sequent searches against said set of ESTs is performed via

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BLAST (second sample set) (page 8, column 2, Modes of access to the MGI data §) and up to 20 hits are displayed in order of significance (ranking and threshold) (page 8, column 1, lines 20-21). The sample sets are illustrated in Figures 4-7, as in instant claims 16, 24, and 28.

CLAIM REJECTIONS - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 15-28, and 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckman et al. (1998) taken with Schena et al. (1996).

13. Eckman et al. (1998) discloses the limitations to claims 1, 15, 16, 21-24, 28, and 35-37 as discussed above.

14. However, Eckman et al. (1998) discloses all of the limitations to claims 17-20, 25-27, and 38-41.

15. Schena et al. discloses the selection of EST sequences according their relative expression values wherein the presence or absence of genes (EST) is determined by the expression of genes compared to control. The selection criteria is novel sequences exhibits either 2-fold induction or relatively low-level expression (page 10615, columns 1-2, Results §, Figures 1, 2; and Tables 1 and 2), as in instant claims 17-20, 25-27, and 38-41.

16. Schena et al. suggests an improvement for better understanding the human genome via the implementation of sophisticated methods for gene expression analysis and gene discovery

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using EST sequences (page 10614, column 1, lines 1-22). While Eckman et al. discloses a method of effective use of the vast amounts of EST sequence data (Abstract etc.). An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclose by Schena et al. to utilize the vast amounts of EST data disclosed by Eckman et al. for sequence analysis and gene discovery. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of gene expression analysis and gene discovery as taught by Schena et al. and Eckman et al.

CONCLUSION

17. NO CLAIM IS ALLOWED.

18. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.


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21. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
2/9/04


ARDIN H. MARSCHEL
PRIMARY EXAMINER